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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,449

04/04/2007

Yow-Pin Lim

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EXAMINER

MOHAMED, ABDEL A

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

06/19/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,449	LIM ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,10,12-15,21,25,27,28,31,40-42,45-48,56,57,77-86,88,96,98,99 and 101.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,2,10,12-15,21,25,27,28,31,40-42,45-48,56,57,77-86,88,96,98,99 and 101.

ACKNOWLEDGEMENT TO THE PRELIMINARY AMENDMENT AND THE STATUS OF THE CLAIMS

The preliminary amendment filed 05/04/06 is acknowledged, entered and considered. In view of Applicant's request claims 2, 10, 12-15, 21, 25, 27, 28, 31, 47, 48, 56, 57, 77, 78, 80, 81, 89, 98 and 101 have been amended and claims 3-9, 11, 16-20, 22-24, 26, 29, 30, 32-39, 43, 44, 49-55, 58-76, 87, 89-95, 97 and 100 have been canceled. Claims 2, 10, 12-15, 21, 25, 27, 28, 31, 47, 48, 56, 57, 77, 78, 80, 81, 88, 98 and 101 are active and pending in the application.

ELECTION/RESTRICTION

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 10, 12-15, 21, 25, 27, 28, 31, 40-42, 45-48, 56, 57 and 77-86 and 101, drawn to a process for producing a blood plasma-derived I-alpha-Ip (Ialp) and P-alpha-I (Pal) composition comprising a mixture of inter-alpha inhibitor protein (Ial) and pre-alpha protein (Pal), pharmaceutical and kit formulation thereof and to a method of treating an inflammation related disorder, cancer and infectious disease in a subject.
an inflammation related disorder, cancer and infectious disease in a subject.

Group II, claim(s) 88, drawn to a method of treating a subject for acute inflammatory disease by determining the pre-treatment level of inter-alpha inhibitor protein and administering an effective amount of I-alpha-Ip to treat the subject.

Group III, claim(s) 96, drawn to a method for predicting a response to an I-alpha-Ip therapy by assaying a sample of inter-alpha inhibitor proteins.

Group IV, claim(s) 98, drawn to a method for monitoring the progress of a subject being treated with an I-alpha-Ip therapy by determining the pre-treatment level of inter-alpha inhibitor proteins and administering an effective amount of I-alpha-IP.

Super Group V, claim(s) 99, drawn to a kit for therapy having $8! = 40,320$ possible kits.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The methods of Groups I-IV each has different scope, they are directed to various methods of using the compositions (i.e., inter-alpha inhibitor proteins from human plasma) for different purposes. Although, Inventions I-IV are related, the end results of the aforementioned treatment and use of kit or prediction or monitoring are divergent and a search conducted for one would not necessarily overlap with a search conducted for another.

Art Unit: 1654

Further, Inventions I-IV each differ from the other in a method of treating an inflammation related disorder, cancer and infectious disease in a subject and a kit formulation thereof (Group I), a method of treating a subject for acute inflammatory disease (Group II), a method for predicting a response to an I-alpha-Ip therapy (Group III), a method for monitoring the progress of a subject being treated with an I-alpha-Ip therapy (Group IV). Thus, the various methods using the same compositions/formulations as recited above do not correspond to the same technical feature and are not connected in design, operation or effect because they differ in method steps, parameters and reagents used, and as such, the methods as grouped are different from each other because they represent different technical features and different endeavors. Thus, the method of treating and use of a kit differs from the method for predicting or the method for monitoring and *vice versa* because the methods do not correspond to the same technical features and are not connected in design, operation or effect. Therefore, Groups I-IV do not share the same special technical features, the inventions do not relate to a single inventive concept.

With respect to Super Group V, the group has $8! = 40,320$ possible kits, and as such, there is no unity of invention between all the possible kits. If Applicant elects Super Group V, then, Applicant has to choose or pick or elect **only one kit** among the possibility of 40,320 kits. **This is NOT a species election but a restriction election within the Super Group.**

Art Unit: 1654

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

CONCLUSION AND FUTURE CORRESPONDANCE

Claims 1, 2, 10, 12-15, 21, 25, 27, 28, 31, 40-42, 45-48, 56, 57, 77-86, 88, 96, 98, 99 and 101 are subject to restriction and/or election requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272-0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mohamed/A. A. M./
Examiner, Art Unit 1654

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657